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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,539	02/03/2005	Kenji Sunagawa	KUP-5	7546
20808 7590 02/07/2008 BROWN & MICHAELS, PC 400 M & T BANK BUILDING 118 NORTH TIOGA ST ITHACA, NY 14850			EXAMINER KAHELIN, MICHAEL WILLIAM	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 02/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,539	Applicant(s) SUNAGAWA ET AL.	
	Examiner MICHAEL KAHELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-18 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 7-12, drawn to a system that discriminates between normal and abnormal activities based on convolutions.

Group II, claim(s) 7-11, 13, and 14, drawn to a system that stimulates the heart based on a convolution of a nerve signal.

Group III, claim(s) 15-17, drawn to a system that stimulates a sympathetic nerve signal based on blood pressure.

Group IV, claim(s) 18, drawn to a system that stimulates a nerve based on cardiovascular activity.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common feature of sensing biological activity, calculating stimulation signals, and stimulating tissue based on the signals does not qualify as a "special technical feature" because it does not make a contribution over the prior art. See, e.g., *Marcovecchio* (US 6,223,078).

3. During a telephone conversation with Meghan Van Leeuwen on 2/4/2008 a provisional election was made without traverse to prosecute the invention of I, claims 7-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 7-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Marcovecchio (US 6,223,078, hereinafter "Marcovecchio").

7. In regards to claims 7 and 12, Marcovecchio discloses a biological activity sensing means (col. 2, lines 41-48), a calculating means that calculates a stimulation signal (elements 250 and/or 540) using a convolution between the biosignal and previously obtained activities (col. col. 3, lines 8-27), and a stimulating means that stimulates with the signals from the calculating means (elements 250 and/or 540). Further, the device discriminates between normal and abnormal biological activities (elements 240 and/or 536) and applies stimulation accordingly. Examiner is considering "VT complexes" exceeding the threshold to be "abnormal" and "VT complexes" not exceeding the threshold to be a "normal" number of "VT complexes."

8. In regards to claim 8, the sensing means is an electrode (col. 5, lines 23-26).

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9. In regards to claim 9, the biosignals are ECG signals (col. 2, line 40).
10. In regards to claim 10, the device applies electrical therapy (col. 4, line 14).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 11 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Marcovecchio. Marcovecchio discloses that the system comprises an amplifier (712 and 714) and a microprocessor analyzer to process data (724). Although not explicitly depicted in Figure 7, the microprocessor-based system inherently requires an A-D converter to allow the analog heart signals to be manipulated by the digital microprocessor.

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14. Alternatively, Marcovecchio discloses the essential features of the claimed invention except for explicitly disclosing an A-D converter. It is notoriously well known in the implantable device arts to provide A-D converters to allow analog biological signals to be manipulated by versatile and inexpensive digital microprocessors. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Marcovecchio's invention with an A-D converter to provide the predictable result of allowing analog biological signals to be manipulated by versatile and inexpensive digital microprocessors.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

mkp
2/5/08

GEORGE R. EVANISKO
PRIMARY EXAMINER

2/1/9